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☒ Applicant claims small entity status. See 37 CFR 1.27

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Complete if Known

Application Number	09/733,611
Filing Date	December 8, 2000
First Named Inventor	Waheguru Pal Singh
Examiner Name	Sabiha Naim Qazi
Art Unit	1616
Attorney Docket No.	LYNN/0120

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1202	18	2202	9	Claims in excess of 20
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1203	290	2203	145	Multiple dependent claim, if not paid
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1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	165.00
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
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1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
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1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

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SUBMITTED BY

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Signature	<i>[Signature]</i>	Date	September 7, 2004		

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TRANSMITTAL FORM

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Application Number	09/733,611	
	Filing Date	December 8, 2000
	First Named Inventor	Waheguru Pal Singh
	Art Unit	1616
	Examiner Name	Sabiha Naim Qazi
Attorney Docket Number	LYNN/0120	
Total Number of Pages in This Submission	86	

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Firm or Individual name	Frank J. Campigotto
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Brief of Appellants
Attorney. Dkt. No. LYNN/0120

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IN RE APPLICATION OF:

Waheguru Pal Singh, *et al.*

SERIAL NO. 09/733,611


FILED: December 8, 2000

FOR: Methods of Sterilizing with
Dipercarboxylic Acids

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EXAMINER: Qazi, Sabiha Naim

GROUP ART UNIT: 1616

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BRIEF OF APPELLANTS

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Appellants timely filed a Notice of Appeal to this Board on August 24, 2004 appealing the decision of the Examiner in the Final Office Action dated February 26, 2004, for the above captioned application. Appellants hereby submit this Brief of Appellants, in triplicate, pursuant to 37 CFR 1.192.

(1) REAL PARTY IN INTEREST

The real party of interest in this action is Lynntech International, Ltd., the recorded assignee of the entire right, title and interest in and to the patent application now under appeal before this Board. Lynntech International, Ltd. is a limited partnership of the State of Texas having a place of business at College Station, Texas.

(2) RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellants, Appellants' legal representative, or Assignee that will affect or be directly affected by or have a bearing upon the Board's decision in the pending appeal.

(3) STATUS OF THE CLAIMS

The status of all pending claims in the application under appeal is as follows: claims 1-11, 17 and 26- 51 are pending and stand rejected. Rejected claims 1-10, 17, 26-38, 40-49 and 51 are under appeal. Claims 11, 39 and 50 are not appealed. Claims 12-16 and claims 18-25 have been cancelled as the result of a restriction requirement by the Examiner and are not pending.

(4) STATUS OF AMENDMENTS

On May 10, 2004 Appellants filed a response to the Final Office Action from which this appeal is taken. Appellants did not request entry of any new amendments at that time. There are no pending amendments to the claims outstanding.

(5) SUMMARY OF THE INVENTION

Appellants identified a need for methods that would provide effective sterilizing solutions. (Specification, p. 3, ln. 19-24). An effective sterilizing solution is one that is without cause for concern as to the stability or shelf-life of the sterilizing solution or its transportation as a hazardous and bulky solution. *Id.* Appellants determined that a desirable sterilizing solution would be one that (1) could be formed from a stable, solid peracid formulation, (2) did not contain the reagents or chemicals used in formation of the peracid, and (3) could be formed from a peracid that was soluble enough in water to obtain an aqueous solution having a peracid concentration high enough to be a sterilizing solution. *Id.*

Peracids are potent biocides that have a broad-spectrum killing potential that decompose upon use into chemically benign end products. (Specification, p. 2, ln. 11-15). Prior art formulations of peracid sterilizing solutions contained low molecular weight peracids that were pungent and possessed high volatility. *Id.* As Appellants pointed out, by citing Eggersperer, *et al.*, U.S. Patent No. 4,129,517, those having ordinary skill in the art believed that peracids having a molecular weight high enough to form a stable solid could not be dissolved in water at concentrations high enough to form a sterilizing solution. *Id.* at 19-28.

However, contrary to the beliefs of Eggersperer and others, Appellants found that there are peracids that are stable as a solid at room temperature and that can be dissolved at concentrations high enough to form aqueous sterilizing solutions. (Specification, p. 3, ln. 28-30). Solutions made with these dipercarboxylic acids are characterized by effectiveness against a broad spectrum of microorganisms, including but not limited to mycobacteria, yeasts, fungi, viruses and resistant bacteria spores. (Specification, p. 4, ln. 5-10).

To understand the value of this invention, it is imperative to distinguish between sterilization and disinfection – sterilization uses physical or chemical means to destroy all microbial life while disinfection destroys some, but not all microbial life. *Id.* at 11-15. If a chemical disinfectant can reduce the level of bacterial endospores by six logarithms or more, it is considered to be a liquid sterilant. *Id.* at 19-21. Appellants demonstrated that certain solid dipercarboxylic acids were soluble in water at sterilization levels. (Specification, p. 9, ln. 1-5 and FIG. 1). In FIG. 1, Appellants further showed that a 10% diperglutaric acid solution killed all spores almost immediately and that a 0.8% dipersuberic solution killed all spores after about 10 minutes of exposure to the sterilizing solution by the spores. (Specification, FIG. 1). Therefore, Appellant demonstrated that certain dipercarboxylic acids could be formed into a solid and then dissolved in water at sufficient concentration to form a sterilizing solution.

Appellants claim a method of preparing a sterilizing solution that includes storing dry solid material that comprises one or more dipercarboxylic acids and dissolving this material into water as needed to prepare an aqueous sterilizing solution having a dipercarboxylic acid concentration between about 0.1 wt% and saturation. (Claim 1).

The select subset of dipercarboxylic acids are unique sterilizing agents because they can form dry solid particulates at ambient conditions, yet are readily dissolved in water with minimal agitation, such as stirring. (Specification, p. 7, ln. 1-4). Furthermore, this subset of dipercarboxylic acids can be stored as a solid for extended periods without degradation. *Id.* Examples of dry dipercarboxylic acids that may be used in the claimed method of Appellants include diperglutaric acid (C5), diperadic acid (C6), diperpimelic acid (C7), dipersuberic acid (C8), and diperazelaic acid (C9). (Specification, p. 4, ln. 4-5). The parenthetical “C” number provides the number of carbon atoms in the dipercarboxylic acid.

Because the dipercarboxylic acids used in the method of the present invention to form a sterilizing solution are first stored as a dry solid, the solid material that comprises one or more dipercarboxylic acids is substantially free from other organic compounds other than the dipercarboxylic acids. (Claim 4). One of the problems of the prior art peracid sterilizing solutions was that these solutions also contained hydrogen peroxide, which was part of the equilibrium mixture resulting from the formation of the peracid. (Specification, p. 3, ln. 10-18). For example, commercially available preparations of peracetic acid contain from 7 to 25 % hydrogen peroxide and from 6 – 40 % acetic acid. *Id.* Appellants specifically claim that the sterilizing solution is free of hydrogen peroxide. (Claim 6). Alternatively, Appellants claim that the solid dry material comprises sterilizing agents consisting essentially of one or more dipercarboxylic acids, thereby excluding hydrogen peroxide as well as any other active sterilizing agent. (Claim 41).

Therefore, the claims under examination provide methods for the preparation of sterilizing solutions that include, *inter alia*, the steps of storing a dry solid material comprising dipercarboxylic acids and dissolving this material into water to form an aqueous sterilizing solution (Claims 1, 30) and in another claimed embodiment, storing dry material comprising sterilizing agents consisting essentially of one or more dipercarboxylic acids. (Claim 41).

(6) ISSUES

The issues upon appeal are as follows:

(a) whether claims 1-10, 17, 26-38, 40-49 and 51 should stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,674,538 of Lokkesmoe, *et al.* (hereinafter Lokkesmoe) in view of U.S. Patent No. 4,013,581 of Huber (hereinafter Huber);

(b) whether claims 1-10, 17, 26-38, 40-49 and 51 should stand rejected under 35 U.S.C. 102(a) as being unpatentable over U.S. Patent No. 5,674,538 of Lokkesmoe, *et al.* in view of U.S. Patent No. 5,753,770 of Breitenbach, *et al.* (hereinafter Breitenbach).

(7) GROUPING OF THE CLAIMS

a. Claims 1-10, 17, 26-38 and 40 are directed to a method of preparing a sterilizing solution from a dry solid material that comprises one or more dipercarboxylic acids. The claims in this group stand or fall together.

b. Claims 41-49 and 51 are directed to a method of preparing a sterilizing solution from a dry solid material comprising sterilizing agents consisting essentially of one or more dipercarboxylic acids. The claims in this group stand or fall together.

(8) ARGUMENT

A. Applicable Law

A claimed invention is unpatentable if the differences between it and the prior art “are such that the subject matter *as a whole* would have been obvious at the time the invention was made to a person having ordinary skill in the art.” 35 U.S.C. 103(a) [emphasis added]. The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966).

To establish a *prima facie* case of obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 985 (CCPA

1974). All words in a claim must be considered in judging the patentability of that claim against the prior art. *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970).

An additional requirement for providing a *prima facie* case of obviousness is that the Examiner must provide a basis for combining or modifying the cited references. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990).

The case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching, suggestion, or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing “teaching or suggestion or motivation [to combine]” as an “essential evidentiary component of an obviousness holding”); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1225, 1232 (Fed. Cir. 1998) (“the Board must identify specifically....the reasons one of ordinary skill in the art would have been motivated to select the references and combine them”); and *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination “only by showing some objective teaching [leading to the combination]”).

In the case *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002), the Federal Circuit held:

When patentability turns on the question of obviousness, the search for and analysis of the prior art includes *evidence* relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness.

Id. at 1343, emphasis added.

Evidence of a suggestion, teaching or motivation to combine references may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1630 (Fed. Cir. 1996). The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985).

In the case *In re Kotzab*, 217 F.3d 1365 (Fed. Cir. 2000), the Court states:

Most, if not all inventions arise from a combination of old elements . . . Thus, every element of a claimed invention may often be found in the prior art. However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant.

Id. at 1395.

The *Kotzab* Court further distinctly points out the requirement that particular findings are required as to the justification of combining references. The Court stated:

Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference. The motivation, suggestion or teaching may come explicitly from statement in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved. In addition, the teaching, motivation or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references . . . The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art . . . Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. Broad conclusory statements standing alone are not evidence.

Id. at 1370.

Further considering the impermissible use of hindsight obviousness analysis in the case

In re McLaughlin, 443 F.2d 1392 (CCPA 1971), the Court stated:

It should be too well settled now to require citation or discussion that the test for combining references is not what the individual references themselves suggest but rather what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. Any judgment of obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made *and does not include knowledge gleaned only from applicant's disclosure*, such a reconstruction is proper.

Id. at 1395, emphasis added.

B. Analysis

Issue (a): Whether claims 1-10, 17, 26-38, 40-49 and 51 should stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,674,538 of Lokkesmoe, *et al.* (hereinafter Lokkesmoe) in view of U.S. Patent No. 4,013,581 of Huber (hereinafter Huber).

Lokkesmoe Disclosure: Lokkesmoe disclosed a process for use by the food processing industry to prevent microbial growth by applying percarboxylic acids to the water streams that are used to transport fruits and vegetables through the processing environment. (Lokkesmoe, Abstract). Given the nature of the food as well as the presence of sediments and soluble material, this transport water and other processing equipment may be subject to the growth of unwanted microorganisms that build up on surfaces in the form of slime or biofilm. (Lokkesmoe, col. 2, ln. 7-16).

Lokkesmoe disclosed that in the past, the food industry used chlorine compounds to control microbial growth in the water streams, using compounds such as sodium hypochlorite and chlorine dioxide, but these compounds created toxic byproducts and were difficult to handle.

(Lokkesmoe, col. 3, ln. 21-35). Therefore, Lokkesmoe sought to solve a problem in the food industry of controlling microbial growth in the transport water streams and equipment without the use of chlorinated or other halogen compounds. *Id.* at 43-48.

Lokkesmoe disclosed many beneficial peracids that may be used, the preferred peracid being peracetic acid, which Lokkesmoe disclosed as having an acrid odor. (Lokkesmoe, col. 5, ln. 1-35). Lokkesmoe only disclosed use of these peracids in liquid form, showing how to form the acids in liquid form by mixing the parent acid with hydrogen peroxide and waiting for eight days to allow the solution to reach equilibrium. (Lokkesmoe, col. 15, ln. 28-37). All of the liquid acids formed show a concentration of hydrogen peroxide in their formulated liquid solution, ranging from 1.5 wt% to 10.5 wt%. (Lokkesmoe, col. 15, Table 18).

Lokkesmoe disclosed that useful concentrations of the constituents making up the composition containing peracids that could be added to the transport water included 2-25 wt% percarboxylic acid, 1-45 wt% hydrogen peroxide, and 1-70 wt% carboxylic acid. (Lokkesmoe, col. 7, ln. 50-65). Useful concentrations of the percarboxylic acids in the transport water were disclosed as being from 5-100 ppm percarboxylic acid. *Id.* Lokkesmoe disclosed that the peracids being used to control slime in the transport water streams of the food processing industry are being used as a sanitizer. (Lokkesmoe, col. 5, ln. 17-18). Lokkesmoe defines a sanitizer and a disinfectant as agents that provide antibacterial or bacteriocidal activity. (Lokkesmoe, col. 4, ln. 10-12). Lokkesmoe does not teach, suggest or disclose any information concerning sterilants or liquid sterilants.

Huber Disclosure: Huber disclosed the use of peroxygen bleaches, especially from diperazelaic acid, provided in tablet form useful for bleaching fabrics. (Huber, Abstract). Huber disclosed that to be an effective bleach, the peracid must have a solubility in water that is high

enough to provide concentrations of between about 5 ppm and 200 ppm, more preferably between about 20 ppm and about 70 ppm of available oxygen in the aqueous bleaching bath. (Huber, col. 5, ln. 9-13).

The prior art references cited by the Examiner do not teach or suggest each and every limitation claimed by Appellants. To establish a *prima facie* case of obviousness, all the claimed limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d at 985. All words in a claim must be considered in judging the patentability of that claim against the prior art. *In re Wilson*, 424 F.2d at 1385. Appellants claim a method of preparing a sterilizing solution comprising (1) storing dry solid material comprising one or more dipercarboxylic acids or, in a second claimed embodiment, (2) comprising sterilizing agents consisting essentially of one or more dipercarboxylic acids. (Claims 1, 41). Appellants further claim dissolving the material into water as needed to prepare a sterilizing solution having a dipercarboxylic acid concentration between about 0.1 weight percent and saturation. (Claims 1, 41).

Neither Lokkesmoe nor Huber teach nor suggest Appellants' claimed limitation of dissolving a dry solid material having a dipercarboxylic acid in water at a concentration of between about 0.1 weight percent and saturation. Lokkesmoe discloses using only *liquid* peracids, not solid peracids to be dissolved in water. Furthermore, all the concentrations of percarboxylic acids disclosed by Lokkesmoe are in the range of about 5 to about 100 ppm, not the 0.1 wt% (1000 ppm) claimed by Appellants. Huber only teaches or suggests that the concentration of dipercarboxylic acids in water be high enough to provide bleaching action – between 5 and 200 ppm, again not the 0.1 wt% (1000 ppm) claimed by Appellants.

As explained by Appellants in the specification, to understand the value of Appellants' invention, it is imperative to distinguish between sterilization and disinfection. (Specification, p.

4, ln, 10-21). Sterilization destroys all microbial life or, as a liquid sterilant, at least reduces the level of bacterial endospores by six logarithms or more. *Id.* Disinfection, meanwhile, only destroys most life but not spores. *Id.* These definitions used by Appellants are within the common meaning as understood by those having ordinary skill in the art. For example, in the McGraw-Hill *Dictionary of Scientific and Technical Terms*, 6th Edition, 2003, sterilization is defined as “An act or process of destroying all forms of microbial life on and in an object” and a disinfectant is defined as “A chemical agent that destroys microorganisms but not bacterial spores.” *Id.*

Appellants claim concentrations of dipercarboxylic acids that are necessary to produce a sterilizing liquid, defined as a solution that is capable of reducing the level of bacterial endospores by six logarithms or more. As previously discussed in § 5, *supra*, Appellants demonstrated and disclosed in their Specification that certain dipercarboxylic acids could be formed into a stable solid that could be stored and then dissolved in water at sufficient concentration to form a sterilizing solution that killed *all* spores.

As the courts have instructed, all words in a claim must be considered in judging the patentability of that claim against the prior art. *In re Wilson, supra*. There is simply no teaching or suggestion in either Lokkesmoe or Huber that a sterilizing solution can be formed from *solid* percarboxylic acids at concentrations above 0.1 wt% as claimed by Appellants.

Because neither of the prior art references cited by the Examiner teach or suggest that a solid dipercarboxylic acid can be dissolved in water at concentrations of between 0.1 wt% and saturation, or that such a concentration could form a sterilizing solution, Appellants respectfully assert that the cited prior art references do not teach or suggest each and every limitation claimed

by Applicant as required for a *prima facie* case of obviousness. Therefore, Appellants respectfully request that the Board find that claims 1-10, 17, 26-38, 40-49 and 51 are patentable.

There has been no evidence of a teaching or suggestion to combine or modify the prior art references cited by the Examiner. As the Federal Circuit has taught, to find obviousness, there must be *evidence* presented relevant to the finding of whether there is a teaching, motivation or suggestion to select and combine the prior art references. *In re Lee*, 277 F.3d at 1343, emphasis added. Broad conclusory statements standing alone are not evidence. *In re Kotzab*, 217 F.3d at 1370. Evidence of a suggestion, teaching or motivation to combine references may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1630 (Fed. Cir. 1996). The Examiner must be careful not to fall into the hindsight trap. The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985).

The Examiner has stated that it would be obvious to one skilled in the art to be motivated at the time of invention to prepare additional beneficial antimicrobial composition especially when prior art teaches the antimicrobial formulation using a solid dipercarboxylic acid. (Office Action dated May 30, 2002). The Examiner goes on to state that the motivation is that the prior art teaches solid peroxydicarboxylic acids for preparing tablets. *Id.*

First, Appellants respectfully point out that the cited prior art references do not disclose, suggest or teach that any solid dipercarboxylic acid may be dissolved into water at high enough concentrations to form a sterilizing solution, which are limitations claimed by Appellants. Disclosing that a compound may be dissolved into water at a low level of concentration, up to

about 200 ppm for use as a bleach or up to 100 ppm for use as a sanitizer as disclosed by the prior art, does not teach or suggest that the same composition may be dissolved into water at concentrations exceeding 1000 ppm, which is the limitation (0.1 wt%) claimed by Appellants. One having ordinary skill in the art, at the time Appellants conceived their invention, did not realize that stable solid peracids could be dissolved at high enough concentrations in water to form a sterilizing solution. It is against this benchmark, the state of the art as it existed at the time of the invention, that obviousness must be measured. *Interconnect Planning Corp., supra*.

Appellants respectfully assert that such a broad conclusory statement as the one made by the Examiner is not the evidence required by the courts to find that there is a teaching, suggestion or motivation to combine or modify the prior art references. Instead, Appellant respectfully asserts that the Examiner has fallen into the hindsight trap, using Appellants specification as a blueprint. As the courts have held, the invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time. *Interconnect Planning Corp. v. Feil*, 774 F.2d at 1138.

The Federal Circuit Court has taught that the evidence of a suggestion, teaching or motivation to combine references may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art or the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d at 1537.

Neither of the cited references identified the problem that Appellants solved – identifying a compound that could be stored as a dry material and then dissolved in water in high enough concentrations to form a sterilizing solution, thereby making it unnecessary to transport and store bulky liquid volumes of often hazardous sterilizing solutions. Lokkesmoe only disclosed liquids that could be used as slime control agents in water transport streams of the food industry.

Lokkesmoe did not suggest or teach that there was a need for sterilizing agents. Huber disclosed bleach compositions and did not discuss, suggest or disclose that any of the compounds disclosed by Huber could be used as a sterilizing agent that could be stored as a solid and then dissolved when a sterilizing solution was required. Neither of the cited references taught, suggested or provided motivation to determine whether any dipercarboxylic acids could be dissolved in water at high enough concentrations to form a sterilizing solution.

Appellants respectfully assert that the motivation asserted by the Examiner to combine or modify these cited references is based solely upon Appellants' Specification. Without Appellants' Specification as a guide, there is no motivation, suggestion or teaching to combine or modify the prior art references cited by the Examiner. As the *Rouffet* court held, *supra*, the reasons one of ordinary skill in the art would have been motivated to select the references and combine them must be identified specifically. *In re Rouffet*, 149 F.3d at 1359.

The problems sought to be solved by Appellants and the cited references are not the same. Furthermore, as pointed out by Appellants, *supra*, those having ordinary skill in the art did not recognize that there were peracids that could be formed and stored as a solid and then dissolved into water when needed at concentrations sufficient to form a sterilizing solution. Finally, the prior art references themselves provide no teaching or suggestion to modify or combine the cited prior art references.

Having failed to provide evidence of a suggestion, teaching or motivation to combine or modify the prior art references to the claimed invention of the Appellants, Appellants respectfully assert that a *prima facie* case of obviousness has not been presented. Therefore, Appellants respectfully request the Board to find that claims 1-10, 17, 26-38, 40-49 and 51 are patentable.

Issue (b): Whether claims 1-10, 17, 26-38, 40-49 and 51 should stand rejected under 35 U.S.C. 102(a) as being unpatentable over U.S. Patent No. 5,674,538 of Lokkesmoe, *et al.* in view of U.S. Patent No. 5,753,770 of Breitenbach, *et al.* (hereinafter Breitenbach).

Lokkesmoe Disclosure: Discussed under Issue (a), *supra*.

Breitenbach Disclosure: Breitenbach disclosed a process for formulating compositions that are solid complexes of dipercarboxylic acids and hydrogen peroxide, made by applying a solution of hydrogen peroxide and a dipercarboxylic acid to a pulverulent or pregranulated matrix and then drying the resulting mix in a fluidized bed drier. (Breitenbach, Abstract). For this formulation, the matrix is N-vinylpyrrolidone homopolymers. (Breitenbach, col. 2, ln. 17-19). These hydrogen peroxide and percarboxylic acid complexes supported on a homopolymer matrix are disclosed as being useful as, *inter alia*, disinfectants or preservatives in toothpastes, in the treatment of acne, as wound dressings, in cosmetics (hair coloring, hair bleaching) and in depilation. (Breitenbach, col. 6, ln. 30-36).

Examples are disclosed of various solid complexes of peracids and hydrogen peroxide that show the complexes lose 12 % of their peracetic acid content in 4 hours at 70 °C in one case and 10 % of their peracetic acid content after 7 hours at 70 °C. (Breitenbach, col. 9, ln. 41-45 and col. 10, ln. 13-15).

The prior art references cited by the Examiner do not teach or suggest each and every limitation claimed by Appellants. Appellants claim a method of preparing a sterilizing solution comprising (1) storing dry solid material comprising one or more dipercarboxylic acids or, in a second claimed embodiment, (2) comprising sterilizing agents consisting essentially of one or more dipercarboxylic acids. (Claims 1, 41). Appellants further claim dissolving the material

into water as needed to prepare a sterilizing solution having a dipercarboxylic acid concentration between about 0.1 weight percent and saturation. (Claims 1, 41).

Neither Lokkesmoe nor Breitenbach teach or suggest Appellants' claimed limitation of dissolving a dry solid material having a dipercarboxylic acid in water at a concentration of between about 0.1 weight percent and saturation. The disclosure of Lokkesmoe and its failure to teach or suggest each and every limitation claimed by Appellant is discussed under Issue (a), *supra*. Breitenbach makes no disclosure of dissolving a dipercarboxylic acid in water at high enough concentrations to obtain a sterilizing solution, as claimed by Appellants.

The Examiner asserts that Breitenbach discloses disinfectants and that a disinfectant is the same as a sterilant. (Office Action, p. 4-5). Citing Merriam-Webster Dictionary, the Examiner states that the terms "disinfectant" and "sterilize" are synonymous because they both mean clean. *Id.* The Examiner, therefore, asserts that Breitenbach's disclosure of disinfectants is by definition, a disclosure of sterilizers. *Id.* Appellants respectfully disagree.

According to the Merriam-Webster online dictionary, a disinfectant is defined as "an agent that frees from infection; *especially* : a chemical that destroys vegetative forms of harmful microorganisms especially on inanimate objects but that may be less effective in destroying bacterial spores." Likewise, the online dictionary defines sterilize as "to free from living microorganisms." Appellants also clearly defined the meaning of these words in their Specification and the definitions provided therein are well known and commonly used by those having ordinary skill in the art. Likewise, as discussed above, these definitions are similar to those provided in the McGraw-Hill *Dictionary of Scientific and Technical Terms*, 6th Edition, 2003, wherein "sterilization" is defined as "An act or process of destroying all forms of

microbial life on and in an object” and a “disinfectant” is defined as “A chemical agent that destroys microorganisms but not bacterial spores.” *Id.*

Breitenbach merely discloses that the compositions disclosed therein containing hydrogen peroxide and dipercarboxylic acids may be used as disinfectants in, *inter alia*, toothpastes and cosmetics. Breitenbach makes no suggestion or teaching that the compounds are useful as a sterilant when dissolved in water or that they may be dissolved in water at a high enough concentration to form a sterilizing solution.

Appellants claim limitations of a sterilant without hydrogen peroxide. Appellants include limitations in some of their claims directed to a sterilizing solution that is substantially free of hydrogen peroxide (Claim 6) and a dry solid material comprising sterilizing agents consisting essentially of one or more dipercarboxylic acids (Claim 41). In either of these two claims, Breitenbach would not be a relevant reference. Sterilants that contain hydrogen peroxide are not within the scope of the claim 6 or claim 41.

Therefore, the prior art references, either alone or in combination, that were cited by the Examiner fail to teach or suggest the limitations of Appellants’ claimed invention of storing a dry solid material having one or more dipercarboxylic acids and dissolving the material into water as needed to prepare a sterilizing solution having a dipercarboxylic acid concentration of between 0.1 % and saturation. In order to present a *prima facie* case of obviousness, each of these limitations must be taught or suggested by the prior art references cited by the Examiner. Because the prior art references fail to teach or suggest each and every limitation claimed by Appellants, Appellants respectfully assert that a *prima facie* case of obviousness has not been presented. Therefore, Appellants respectfully request that the Board find that claims 1-10, 17, 26-38, 40-49 and 51 are patentable.

There has been no evidence of a teaching or suggestion to combine or modify the prior art references cited by the Examiner. The Examiner has provided no evidence of a suggestion, teaching or motivation to combine or modify the cited references as required to provide a *prima facie* case of obviousness. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d at 1573. The Examiner has stated that “there is enough motivation in the cited references to prepare the solution in the presently claimed invention.” (Office Action dated June 18, 2003, p. 6).

This broad conclusory statement provided by the Examiner as to the motivation to select and combine the prior art references is not the type of evidence that is required to provide a *prima facie* case of obviousness. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d at 1573.

The limitations claimed by the Appellants are not provided in the cited prior art references. The problems sought to be solved by the prior art references and by Appellants are not the same. Neither of the cited prior art references teach or suggest that dipercarboxylic acid may be stored in a solid form and later dissolved in water to form a sterilizing solution. There is no motivation to combine these references, but even when combined, these references do not teach or suggest the limitations of the Appellants’ claims.

Therefore, because there is no suggestion, teaching or motivation to combine or modify the cited prior art references, Appellants respectfully assert that a *prima facie* case of obviousness has not been provided. Therefore, Appellants respectfully request that the Board find that claims 1-10, 17, 26-38, 40-49 and 51 are patentable.

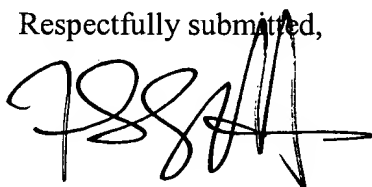
Summary. In summary, the references cited by the Examiner fail to disclose, teach or suggest each and every limitation of the present claims. None of the cited prior art references disclose, teach or suggest that a solid dipercarboxylic acid may be stored and then dissolved in

water at concentrations high enough to form a sterilizing solution, *i.e.*, greater than 0.1 wt%. None of the cited prior art references discuss or recognize sterilizing agents or sterilizing solutions, either generally or specifically. The cited references disclose, teach or suggest only subject matter concerning bleaches and disinfectants.

There is no teaching or suggestion in the cited prior art references that provides a motivation to combine the cited prior art references. The present rejections are based only upon the impermissible use of hindsight analysis utilizing Appellants' Specification as a blueprint.

WHEREFORE, Appellants respectfully request that the Board find that claims 1-10, 17, 26-38, 40-49 and 51 presented on appeal are patentable.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'F. Campigotto', with a long horizontal stroke extending to the right.

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

IN RE APPLICATION OF:	§	
Waheguru Pal Singh, <i>et al.</i>	§	
SERIAL NO. 09/733,611	§	EXAMINER: Qazi, Sabiha Naim
FILED: December 8, 2000	§	
FOR: Methods of Sterilizing with	§	GROUP ART UNIT: 1616
Dipercarboxylic Acids	§	
	§	

APPENDIX IN SUPPORT OF APPELLANTS BRIEF

Claims on Appeal Appendix A

APPENDIX A

CLAIMS ON APPEAL

1. (Original) A method of preparing a sterilizing solution, comprising:
 - (a) storing dry solid material comprising one or more dipercarboxylic acid; and
 - (b) dissolving the dry solid material into water as needed to prepare an aqueous sterilizing solution having a dipercarboxylic acid concentration between about 0.1 weight percent and saturation.
2. (Original) The method of claim 1, wherein the solid material further comprises inorganic salts.
3. (Original) The method of claim 2, wherein the inorganic salts are provided in a stabilizing amount.
4. (Original) The method of claim 1, wherein the solid material is substantially free from organic compounds other than the one or more dipercarboxylic acid.
5. (Original) The method of claim 1, wherein the one or more dipercarboxylic acid is soluble in water in the absence of a solubilizer.
6. (Original) The method of claim 1, wherein the sterilizing solution is substantially free of hydrogen peroxide.
7. (Original) The method of claim 1, wherein the one or more dipercarboxylic acid is selected from diperglutaric acid, diperadipic acid, diperpimelic acid, dipersuberic acid, and diperazelaic acid, and combinations thereof.
8. (Original) The method of claim 1, wherein the amount of solid material dissolved into water is sufficient to be sporicidal.

9. (Original) The method of claim 1, wherein the amount of solid material dissolved into water is sufficient to be sterilizing.

10. (Original) The method of claim 1, wherein the water is at ambient temperature.

11. (Original) The disinfecting solution formed by the method of claim 1.

12-16. (Canceled).

17. (Original) The method of claim 1, wherein the dry solid material further comprises one or more organic solubilizers selected from long chain aliphatic fatty acids, long chain aliphatic quaternary ammonium salts, and combinations thereof.

18-25. (Canceled)

26. (Previously Presented) The method of claim 1, further comprising:
 contacting a surgical instrument with the sterilizing solution, wherein the surgical instrument becomes sterilized.

27. (Previously Presented) The method of claim 1, further comprising:
 contacting a device with the sterilizing solution, wherein the device becomes sterilized.

28. (Previously Presented) The method of claim 1, wherein the step of dissolving further comprises:
 stirring the sterilizing solution, wherein the stirring facilitates the dissolving of the dry solid material.

29. (Previously Presented) The method of claim 1, further comprising:
 contacting a lumen of an endoscope with the sterilizing solution, wherein the lumen becomes sterilized.

30. (Previously Presented) A method of preparing a sterilizing solution, comprising:
- (a) storing dry solid material comprising one or more dipercarboxylic acid; and
 - (b) dissolving the dry solid material into water as needed to prepare an aqueous sterilizing solution having a dipercarboxylic acid concentration between about 0.1 weight percent and saturation, in the absence of a peroxide.
31. (Previously Presented) The method of claim 29, wherein the solid material further comprises inorganic salts.
32. (Previously Presented) The method of claim 30, wherein the inorganic salts are provided in a stabilizing amount.
33. (Previously Presented) The method of claim 29, wherein the solid material is substantially free from organic compounds other than the one or more dipercarboxylic acid.
34. (Previously Presented) The method of claim 29, wherein the one or more dipercarboxylic acid is soluble in water in the absence of a solubilizer.
35. (Previously Presented) The method of claim 29, wherein the one or more dipercarboxylic acid is selected from diperglutaric acid, diperadipic acid, diperpimelic acid, dipersuberic acid, and diperazelaic acid, and combinations thereof.
36. (Previously Presented) The method of claim 29, wherein the amount of solid material dissolved into water is sufficient to be sporicidal.
37. (Previously Presented) The method of claim 29, wherein the amount of solid material dissolved into water is sufficient to be sterilizing.

38. (Previously Presented) The method of claim 29, wherein the water is at ambient temperature.

39. (Previously Presented) The disinfecting solution formed by the method of claim 29.

40. (Previously Presented) The method of claim 29, wherein the dry solid material further comprises one or more organic solubilizers selected from long chain aliphatic fatty acids, long chain aliphatic quaternary ammonium salts, and combinations thereof.

41. (Previously Presented) A method of preparing a sterilizing solution, comprising:

(a) storing dry solid material comprising sterilizing agents consisting essentially of one or more dipercarboxylic acids; and

(b) dissolving the dry solid material into water as needed to prepare an aqueous sterilizing solution having a dipercarboxylic acid concentration between about 0.1 weight percent and saturation.

42. (Previously Presented) The method of claim 40, wherein the solid material further comprises inorganic salts.

43. (Previously Presented) The method of claim 41, wherein the inorganic salts are provided in a stabilizing amount.

44. (Previously Presented) The method of claim 40, wherein the solid material is substantially free from organic compounds other than the one or more dipercarboxylic acid.

45. (Previously Presented) The method of claim 40, wherein the one or more dipercarboxylic acid is soluble in water in the absence of a solubilizer.

46. (Previously Presented) The method of claim 40, wherein the one or more dicarboxylic acid is selected from diperglutaric acid, diperadipic acid, diperpimelic acid, dipersuberic acid, and diperazelaic acid, and combinations thereof.

47. (Previously Presented) The method of claim 40, wherein the amount of solid material dissolved into water is sufficient to be sporicidal.

48. (Previously Presented) The method of claim 40, wherein the amount of solid material dissolved into water is sufficient to be sterilizing.

49. (Previously Presented) The method of claim 40, wherein the water is at ambient temperature.

50. (Previously Presented) The disinfecting solution formed by the method of claim 40.

51. (Previously Presented) The method of claim 40, wherein the dry solid material further comprises one or more organic solubilizers selected from long chain aliphatic fatty acids, long chain aliphatic quaternary ammonium salts, and combinations thereof.